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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,570	05/31/2001	Ming-Hui Wei	CL000900CIP	8055

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/867,570	WEI ET AL.	
	Examiner	Art Unit	
	Jon M. Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4, 8-9, and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.D.D

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 24 June 2005 has been received and entered in full. Claims 4, 8-9, and 24-29 remain pending and are the subject of this Office Action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Objections and/or Rejections

Claim Rejections - 35 USC § 101

3. Claims 4, 8-9, and 24-29 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility, for reasons set forth at pages 3-6 (¶ 5-12) in the previous Office Action (mailed 24 January 2005).

4. The instant application discloses a nucleic acid set forth as SEQ ID NO:1 (transcript) and SEQ ID NO:3 (genomic) that encodes the protein set forth as SEQ ID NO:2, and vectors and host cells comprising the same. The specification asserts that SEQ ID NO:2 is a G protein coupled receptor (GPCR) that is related to the human Mas-related GPCR subfamily based on a high degree of homology to known GPCR sequences (See page 11, line 10-12; Figure 1). The only experimental data or information provided by the Instant Specification is that the nucleic acid encoding SEQ ID NO:2 is expressed in human erythroleukemia cells and testis (See page 11, lines 19-20; Figure 1). The instant specification does not teach any physiologic ligands or

functional characteristics of the GPCR set forth in SEQ ID NO:2 or encoded by the disclosed nucleic acid set forth in SEQ ID NOs:1 and 3, nor does it identify any diseases or disorders that are associated with the claimed molecules. There is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

5. Applicant's arguments (filed 24 June 2005), as they pertain to the rejections have been fully considered but are not found to be persuasive for the following reasons. In the previous Office Action of 24 January 2005, the Examiner made a *prima facie* showing that the claimed invention lacks utility and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (see pages 3-6). Essentially, Applicant has not provided evidence to demonstrate that the claimed polynucleotide of the instant application is supported by a specific and asserted utility or a well-established utility. The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response.

6. Applicants argue at pages 3-4 of the response (filed 24 June 2005) that the specification provides evidence that the claimed nucleic acids encode a G protein-coupled receptor (GPCR) based on the membrane-spanning structure and domains provided in Figure 2, and homology with known Mas-related GPCRs. The Applicants then assert that the functions and diseases associated with Mas-related GPCRs are well known in the art. By way of example, the Applicants assert that Mas-related GPCRs exert oncogenic effects such as by modulating critical components of cell signaling and growth-regulating pathways and are, therefore, associated with

cancer. Thus, the Applicants argue, the claimed molecules are useful for the prevention, diagnosis, and treatment of cancer.

7. Applicant's arguments have been fully considered but they are not persuasive for the following reasons. It is noted that Applicant has not provided any evidence or reference of record to substantiate the allegation that the claimed nucleic acids (SEQ ID NO:1 and SEQ ID NO:3) or the protein encoded by them (SEQ ID NO:2) can be used in the prevention, diagnosis, or treatment of cancer.

> It must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

8. Furthermore, while the Examiner agrees that it is credible that SEQ ID NO:2 is a GPCR, its identification as such is not sufficient to establish either a well-known, or s specific, substantial and credible utility. As stated at pages 5-6 of the previous Office Action (mailed 24 Janaury 2005), the art teaches that the GPCR family is extremely diverse, and that function cannot be predicted merely by identifying a protein as a GPCR. For example, Ji et al., in the Journal of Biological Chemistry 273(28): 17299-17302, teach that there have been nearly 2000 GPCR's reported, which are classifiable into 100 sub families according to sequence homology, ligand structure and receptor function. They further teach that different GPCR superfamily

members are capable of sending signals via alternative signal molecules such as Jak2, phospholipase C, or protein kinase C, and that there are other seven transmembrane domain molecules that are not coupled to G proteins at all. Marchese et al. (Genomics 29:335), teach that IL-8 receptor, neuropeptide Y receptor and Somatostatin receptors are all GPCR's. Thus, although the homology of the GPCR family, especially in the transmembrane domain regions, allows identification of such as GPCRs, mere homology and gene expression is not accepted by those of skill in the art as being predictive of function. Utility must be in readily available form. It is possible that, after further characterization, this protein might be found to have a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease. This further characterization, however, is part of the act of the invention, and until it has been undertaken, Applicant's claimed invention is incomplete. Whereas one could readily employ a putative receptor protein of the instant invention in an assay to identify ligands thereto, or to employ a putative receptor protein or the nucleic acid encoding it of the instant invention in diagnostic methods, the information obtained from such assays would be of little use until one discovers the identity of those physiological processes moderated by that putative receptor. Because the instant specification has failed to identify a physiological process which has been shown to be influenced by the activation or inhibition of the putative receptor protein of the instant invention, an artisan would have no way of predicting what effects the administration of that ligand to organism would have. If one cannot predict the effects that the administration of a ligand of the putative receptor of the instant invention is going to have on an organism, then it is unclear as to what practical or real-world benefit is derived by the public from the identification of that ligand.

9. There is little doubt that, after further characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention, and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

10. The instant claims are drawn to a protein which has undetermined function or biological significance. There is no evidence of record or scientific basis that would support a conclusion that the protein of the instant invention or the nucleic acids encoding it can be used to prevent, diagnose, or treat cancer. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:2 or the polynucleotides encoding it (SEQ ID NOs:1 and 3), the claimed invention is incomplete. In the absence of a knowledge of

the natural ligands or biological significance of this protein (e.g., an associated disease state), there is no immediately obvious patentable use for it.

11. It is believed that all pertinent arguments have been addressed.

Claim Rejections - 35 USC § 112, 1st Paragraph

12. Claims 4, 8-9, and 24-29 also remain rejected under 35 U.S.C. 112, first paragraph for reasons set forth at pages 6-7 (¶13) of the previous Office Action (mailed 24 January 2005). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Summary

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
August 29, 2005

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER